

Notice of Allowability

Application No.

09/934,300

Examiner

S. Devi, Ph.D.

Applicant(s)

TALARICO ET AL.

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to Applicants' amendment filed 11/17/05.
2. ☒ The allowed claim(s) ~~is~~ are 12-19, now renumbered as claims 1-8 respectively.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|---|--|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date _____. |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____. |

ATTACHMENT TO NOTICE OF ALLOWABILITY

Applicants' Amendment

- 1) Acknowledgment is made of Applicants' response filed 06/13/05 and Applicants' amendment filed 11/17/05 in response to the non-final Office Action mailed 07/15/05.

Examiner's Amendment

- 2) An Examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to Applicants, an amendment may be filed as provided by 37 C.F.R. 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee. The authorization to prepare this Examiner's amendment was provided by Ms. Michelle Cunningham and Mr. Murray Spruill in a telephonic interview on 05 December 2005.

This application has been amended as indicated below:

Claim 12 has been amended as indicated below:

--Claim 12. (Currently amended). A method of preparing a ~~solution of a~~ PEGylated hemoglobin solution that is substantially free of contaminants comprising:

- (a) dissolving an activated polyethylene glycol (aPEG) in a solvent suitable for addition to a hemoglobin solution and in which said aPEG is stable;
- (b) filtering said dissolved aPEG through at least one filter which substantially reduces the levels of contaminants in the resulting filtered aPEG solution; and
- (c) combining said resulting filtered aPEG solution of step (b) with a hemoglobin solution.--

Status of Claims

- 3) No claims have been amended via the papers filed 06/13/05.
Claims 12 and 14 have been amended via the amendment filed 11/17/05.
Claim 12 has been further amended via this Examiner's amendment.
Claims 12-19 are pending and are under examination.

Rejection(s) Withdrawn

- 4) The rejection of claim 12 made in paragraph 8 of the Office Action mailed 07/15/05 under 35 U.S.C. § 102(b) as being anticipated by Greenwald *et al.* (*Bioconjugate Chem.* 7: 638-641,

1996), is withdrawn in light of Applicants' amendment to the claim. Greenwald's method differs from the instantly claimed method because it includes an additional lyophilization step, i.e., lyophilization of the filtered activated PEG into a powder/solid and its subsequent dissolution in a solution followed by addition to a haemoglobin solution. There is no filtering step in Greenwald's method after the dissolution of the lyophilized material.

5) The rejection of claim 13 made in paragraph 9 of the Office Action mailed 07/15/05 under 35 U.S.C. § 103(a) as being unpatentable over Greenwald *et al.* (*Bioconjugate Chem.* 7: 638-641, 1996) as applied to claim 12 above, and further in view of Talarico *et al.* (*Biochim. Biophys. Acta* 1476: 53-65, 03 January 2000, already of record), is withdrawn in light of Applicants' amendment to the claim.

6) The rejection of claim 14 made in paragraph 10 of the Office Action mailed 07/15/05 under 35 U.S.C. § 103(a) as being unpatentable over Greenwald *et al.* (*Bioconjugate Chem.* 7: 638-641, 1996) as modified by Talarico *et al.* (*Biochim. Biophys. Acta* 1476: 53-65, 03 January 2000, already of record) as applied to claim 13 above, and further in view of Woghiren *et al.* (*Bioconj. Chem.* 4: 314-318, 1993, already of record) or Blume *et al.* (*Biochimica et Biophysica Acta* 1029: 91-97, 1990) and Maraganore *et al.* (US 5,256,559), is withdrawn in light of Applicants' amendment to the base claim.

7) The rejection of claims 15 and 16 made in paragraph 11 of the Office Action mailed 07/15/05 under 35 U.S.C. § 103(a) as being unpatentable over Greenwald *et al.* (*Bioconjugate Chem.* 7: 638-641, 1996) as modified by Talarico *et al.* (*Biochim. Biophys. Acta* 1476: 53-65, 03 January 2000), Woghiren *et al.* (*Bioconj. Chem.* 4: 314-318, 1993, already of record) or Blume *et al.* (*Biochimica et Biophysica Acta* 1029: 91-97, 1990) and Maraganore *et al.* (US 5,256,559) as applied to claim 14 above, and further in view of Shorr (US 5,900,402), is withdrawn in light of Applicants' amendment to the base claim.

8) The rejection of claims 17 and 18 made in paragraph 12 of the Office Action mailed 07/15/05 under 35 U.S.C. § 103(a) as being unpatentable over Greenwald *et al.* (*Bioconjugate Chem.* 7: 638-641, 1996) as modified by Talarico *et al.* (*Biochim. Biophys. Acta* 1476: 53-65, 03 January 2000, already of record), Woghiren *et al.* (*Bioconj. Chem.* 4: 314-318, 1993, already of record) or Blume *et al.* (*Biochimica et Biophysica Acta* 1029: 91-97, 1990), Maraganore *et al.* (US 5,256,559) and Shorr

(US 5,900,402) as applied to claim 16 above, and further in view of Nho *et al.* (US 5,234,903, already of record), is withdrawn in light of Applicants' amendment to the base claim.

9) The rejection of claim 19 made in paragraph 13 of the Office Action mailed 07/15/05 under 35 U.S.C. § 103(a) as being unpatentable over Greenwald *et al.* (*Bioconjugate Chem.* 7: 638-641, 1996) as modified by Talarico *et al.* (*Biochim. Biophys. Acta* 1476: 53-65, 03 January 2000, already of record), Woghiren *et al.* (*Bioconj. Chem.* 4: 314-318, 1993, already of record) or Blume *et al.* (*Biochimica et Biophysica Acta* 1029: 91-97, 1990), Maraganore *et al.* (US 5,256,559), Shorr (US 5,900,402) and Nho *et al.* (US 5,234,903 - Applicants' IDS) as applied to claim 18 above, is withdrawn in light of Applicants' amendment to the base claim.

Remarks

10) Claims 12-19, now renumbered as claims 1-8 respectively, are allowed.

The limitation 'of step (b)' added by Applicants to claim 1 has inherent support in Examples 3, 4(b) and 4(c) of the instant specification. The limitation 'PEGylated solution' added to claim 12 via this Examiner's amendment has descriptive support at lines 19 and 20 of page 3 of the specification.

11) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center, which receives transmissions 24 hours a day and 7 days a week. The transmission of such papers by facsimile must conform with the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The Fax number for submission of amendments, responses or papers is (571) 273-8300.

12) Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAG or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.Mov>. Should you have questions on access to the Private PAA system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

13) Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (571) 272-0854. A message may

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be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week, which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Lynette Smith, can be reached on (571) 272-0864.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

December, 2005


S. DEVI, PH.D.
PRIMARY EXAMINER